REMARKS

Status of Claims

Claims 2, 3, 8, 9, 22, 39, 42-47, 49, and 50-52 are pending and under examination.

Claims 3, 22, 42, 43 and 49 are allowed.

Claims 50-52 are new, and recite the combinations the Examiner has indicated in the previous Office Action he is willing to accept as enabled, and are discussed in detail in a section entitled "New Claims 50-52" below.

Claims 2, 39, and 47 have been amended to pertain only to subject matter indicated as being patentable by the Examiner in the previous Offiee Action. Specifically, **claim 39** was amended to include the combinations of *cis*-acting elements outlined in new **claims 50, 51, and 52**.

Claims 8, 9, 44, 45, and 46 have been amended to include baek references to the newly added claims.

Application Data Sheet

The Examiner notes in the Final Office Action, dated August 3, 2009, that the Application Data Sheet erroneously states, "This application is a continuation of U.S. Application No. 09/831,272 filed August 13, 2001, which is a §371 National Phase Application of PCT/EP99/08710, filed November 12, 1999".

Applicants have attached hereto an amended Application Data Sheet, which has been corrected to read, "This application is a § 371 National Phase Application of PCT/EP99/08710, filed November 12, 1999." Applicants thank the Examiner for noticing this error.

Claim Rejections - 35 USC § 112, first paragraph

The Examiner has rejected **claims 2, 8, 9, 39 and 44-47** under 35 U.S.C. 112, first paragraph, taking the position that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the

invention commensurate in scope with these claims. Specifically, the Examiner states that the specification is enabling for

1) a chimeric promoter capable of local gene expression in plants upon pathogen infection or pathogen elicitor treatment and induction is between 10 and 15 fold wherein the promoter

comprises 4 copies of SEQ ID NO:11 followed by 4 copies of SEQ ID NO:7,

consists of SEQ ID NO:11,

comprises 4 copies of SEQ ID NO:11, or

comprises one eopy or 4 copies of SEQ ID NO:11 followed respectively by one copy or 4 copies of SEQ ID NO:3 or 4; or

2) a chimeric promoter capable of local gene expression in plants upon pathogen infection and induction is between 15 and 81 fold wherein the promoter comprises

two copies of SEQ ID NO:11,

one copy of SEQ ID NO:11 followed by one copy of SEQ ID NO:7,

4 copies of SEQ ID NO:11 followed by four copies of SEQ ID NO:7,

two copies of SEQ ID NO:3 or 4 followed by two eopies of SEQ ID NO:11, or

two copies of SEQ ID NO:1 *[Applicants note that this is a typographical error, it should read SEQ ID NO:7 – see Example 5]* followed by two copies of SEQ ID NO:11,

but does not reasonably provide enablement for any other embodiment.

The Examiner asserts that there is a lack of predictability in determining which embodiments are productive, because the claims broadly recite components of the

promoter. In other words, one skilled in the art could not predict which combinations of *cis*-elemets would produce certain levels of gene expression.

Applicants respectfully disagree with the Examiner regarding this lack of predictability, but have nonetheless decided to limit the claims to the combinations the Examiner is willing to accept as enabled. Therefore, the amendments to **claims 2, 39, and 47** should render these rejections moot. Specifically, **claims 2, 39, and 47** were amended to recite only those embodiments listed in pages 2 and 3 of the Final Office Action, dated August 3, 2009.

Claims 8, 9, 44, 45, and 46 were rejected as being dependent on an unpatentable base claim; in light of the amendments to **claims 2, 39, and 47**, these rejections are now rendered moot.

Despite having amended the above-referenced claims so as to put them in a condition for allowance, Applicants maintain that the person of ordinary skill having before him the present teaching of combinations of *cis*-elements and results would conclude that they do provide adequate enabling teaching and produce predictable results. The wide variety of combinations presented provides the skilled person with detailed information on how to combine *cis*-elements in order to arrive at promoters with the desired properties.

Applicants are aware that under the precedent of *Regents of the University of California v. Eli Lilly,* 119 F.3d 1559 (Fed. Cir. 1997) and its progeny, there has evolved a detailed written description requirement for chemical and biotechnology patents separate and distinct from what is required under enablement. *Eli Lilly* involved claims directed to DNA sequences for encoding vertebrate and mammalian insulin. The specification

- identified (only) rat insulin DNA and
- a general method for isolating human DNA, which incorporated the method used to obtain the rat DNA.

Although the specification was arguably enabling for the broad claims, the Federal Circuit held that such a description was insufficient to describe human DNA as well as claims relating to broad genera of vertebrate and mammalian insulin DNA. The Court applied the

written description requirement to claims that had no new matter. Compounding the already controversial decision, the panel singled out chemical and biotechnology patents by requiring that the written deseription provide "a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

In many cases, particularly with respect to DNA and proteins, the CAFC and the PTO have applied the requirement in a manner that is more demanding than enablement, effectively rendering it a ***super-enablement requirement***.

In re Wallach, 378 F.3d 1330 (Fed. Cir. 2004) provides an example of the species possession requirement being applied as a super-enablement requirement. In *Wallach,* the species possession requirement denied patent protection to an inventor who had discovered, described and apparently enabled a novel and useful DNA sequence. *Wallach* offered no policy rationale for requiring more than an enabling disclosure for DNA claims.

Today, twelve years after *Lilly* was decided, the CAFC has yet to articulate a cohesive statement of the standard for satisfying the species possession requirement, and has applied it in an inconsistent manner to arrive at irreconcilable outcomes for analogous inventions. In view of the lack of clarity and guidance from the CAFC, it is not surprising that the PTO has struggled in its attempts to interpret and apply *Lilly* and its progeny outside of the specific facts of those cases. As noted above, the heightened disclosure requirement of *Wallach* has not been applied to closely analogous biotechnological inventions involving antibodies and viral genomes.

In 2008, the PTO issued the revised Training Materials which replaced and superseded the earlier guidelines. In many cases, the original and 2008 versions arrive at entirely different conclusions with respect to the patentability of essentially identical claims and specifications, as explained in detail on Holman's Biotech IP Blog. The deep confusion and inconsistency at the PTO is symptomatic of the fundamental flaws in the doctrine itself.

For example, the USPTO's own current Written Description Training Materials (conclude that a broad genus claim reciting an "isolated antibody capable of binding to [a protein identified as] antigen X" satisfies the written description requirement, even though the specification indicates that not one single antibody falling within the scope of the claim has ever been made, and

provides no description of the structural, physical or chemical properties of any antibody falling within the scope of the claim. Training Materials Example 13.

Attempts by the PTO to justify the discrepancy merely serves to illustrate the illogic and unworkability of the species possession requirement, and super written description requirement in general.

In April 2009, the controversy over the written description requirement continued in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. 2009). In that case, the Federal Circuit invalidated claims on written description grounds without discussing enablement. However, it appeared that the Court had difficulty coming up with some explanation as to why the disclosure of some structures, coupled with the description of how to use those structures, failed to provide adequate description. While Ariad claims might be too broad, it becomes apparent to the reader that enablement is the actual concern, and the correct tool for policing claim scope. In a concurrence, Judge Linn stated that the Court's "*engrafting of a separate written description requirement onto section 112, paragraph 1 is* ***misguided***." Using Judge Linn's statements for support, the patentee in *Ariad* requested a rehearing *en banc* on the issue. On August 21, 2009, the Federal Circuit granted the patentee's request. The Court requested additional briefing on two issues:

(i) **whether the first paragraph of section 112 contains a written description requirement separate from an enablement requirement**; and

(ii) if a separate written description requirement is set forth in the statute, the scope and purpose of the requirement.

This foretells that the Court is opening the door to reconsidering and revising the "super" written description requirement it set forth in *Eli Lilly*. Applicants respectfully request the Examiner to decide the issue of enablement not under the faulty standard of *Eli Lilly* but to await new guidance expected under *Ariad*. Applicants believe that the Federal Circuit will dismiss the separate written description requirement. An enabling description of a method for isolating the sequence, and a few detailed examples (species), as presently disclosed, should then be held adequate to support generic claims.

Finally, a test for the inducibility of further *cis*-element combinations is also given in the application on page 28.

Thus, one of ordinary skill in the art can have a reasonable expectation of success for any further combination and can, without undue burden, build promoters with the claimed properties, especially taking into account the guidance presented in the specification as outlined above.

Examiner's Response to Arguments:

The Examiner states, in response to Applicants' arguments in their response to the non-final rejection dated December 22, 2008, that the claimed invention is not commensurate in scope with the claims. This assertion again raises the Examiner's argument that various combinations of *cis*-elements do not produce predictable expression levels. The Examiner believes that "[t]he species provided does not entail a pattern from which one could predict the functionality of related [*cis*-]element combinations. In particular the evidence of record is not clear as to why different arrangements give the expression levels they do." The Examiner further states that this unpredictability is increased "by the recitation in the amendment that the induction is over activation if any by abiotic stress," but "one could not predict at activation level of any of the claimed or disclosed promoters over abiotic stress activation as the specifieation does not disclose how to determine this or what the known levels over abiotic stress are."

For the reasons stated above, Applicants respectfully disagree with the Examiner in her belief that the *cis*-element combinations lack predictability; however, Applicants have nevertheless amended the claims so as to limit their scope to the combinations the Examiner is willing to accept as enabled.

New Claims 50-52

Applicants understand that, in accordance with MPEP § 714.12 and 37 C.F.R § 1.116, amendments after a final rejection are no longer a matter of right. However, it is

respectfully submitted that the amendments and elaims are merely directed to limiting the claims to subject matter previously indicated to be allowable, and to cancellation of subject matter not yet indicated to be allowed, thus placing the application in condition for allowance. Applicants respectfully request that the Examiner enter amendments to pending **claims 2, 3, 8, 9, 22, 39, 42-47, and 49** as complying with Examiner's statement of allowed subject matter in the Final Office Action. Additionally, Applicants respectfully request that the Examiner enter new **claims 50-52**, as these claims also contain subject matter allowed by the Examiner in the Final Office Action. No new subject matter is added.

New **claim 50** pertains to a promoter consisting of a *cis*-element of SEQ ID NO:11 and a minimal promoter with an inducibility of 10-15 fold. This embodiment was explicitly listed by the Examiner as being enabled (Final OA, page 2).

New **claim 51** is drafted in analogy to allowable **claims 3 and 42** and pertains to a promoter with a combination of a *cis*-acting element of SEQ ID NO:11 and *cis*-acting element of any one of SEQ ID NOs:5, 6, 8, 9, 10, 12, and 13. The new claim is supported throughout the application, specifically on page 4, last paragraph, or on page 6, fourth paragraph, or on page 22, third paragraph of the application as published (WO00/029592).

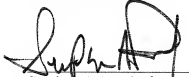
New **claim 52** relates to a promoter that consists of two *cis*-acting elements and a minimal promoter, wherein one of the two elements consists of SEQ ID NO:11. Support for this claim is as indicated above for new **claim 51**.

Accordingly, withdrawal of all rejections and early issuance of allowance is respectfully requested.

The Commissioner is hereby authorized to charge any fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account Number 16-0877.

Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,



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Date: **December 3, 2009**